IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

CENTOCOR ORTHO BIOTECH, INC. AND NEW YORK UNIVERSITY	§	
vs.	§	CASE NO. 2:07-CV-139
ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., AND ABBOTT BIOTECHNOLOGY LTD.	§	

MEMORANDUM OPINION AND ORDER

I. Introduction

Pending before the court is Abbot Laboratories, Abbot Bioresearch Center, Inc., and Abbot Biotechnology Ltd.'s (collectively, "Abbott") motion for summary judgment (Dkt. No. 163). In its motion, Abbott asserts that Centocor Ortho Biotech, Inc., and New York University (collectively, "Centocor") are entitled to a priority date of no earlier than February 4, 1994, with respect to the patents-in-suit, United States Patent Nos. 7,070,775 ("the '775 patent") and 7,276,239 ("the '239 patent"). Abbot further asserts that all of the asserted claims of the patents-in-suit are invalid as anticipated under 35 U.S.C. § 102(b).

Abbott premises its argument upon the doctrine of acquiescence. Generally, Abbott argues that Centocor, through its actions before the United States Patent and Trademark Office ("PTO") during the prosecution of the patents-in-suit, acquiesced to a priority date of no later than February 4, 1994. Centocor's acquiescence purportedly transpired through its abandonment of a parent application and the subsequent filing of a continuation-in-part ("CIP") application in the face of an examiner's 35 U.S.C. § 112 (first paragraph) rejection. The court has considered the evidence and arguments of the parties. For the reasons discussed herein, the court grants

Abbott's motion for summary judgment that Centocor is entitled to a priority date of no later than February 4, 1994. The court denies Abbott's motion that all of the asserted claims of the patents-in-suit are invalid as anticipated under 35 U.S.C. § 102(b).

II. Factual and Procedural Background

In this case, Centocor contends that Abbott infringes various claims of the '775 and '239 patents. Both patents are titled "Recombinant A2-Specific TNFα-Specific Antibodies" and share the same written disclosure.[1] These patents are directed towards anti-Tumor Necrosis Factor ("TNF") antibodies, fragments, and regions thereof which are specific for human tumor necrosis factor-α ("TNF-α") and are useful in diagnosing and treating a number of TNF-α-mediated pathologies and conditions. *See* '775 patent, Abstract.

The patents-in-suit culminate from an extensive and active prosecution history, spanning fourteen patent applications across a fifteen-year period.[2] Centocor filed its original application, U.S. Patent Application No. 07/670,827 ("the '827 application) on March 18, 1991. Centocor then filed a CIP application from the '827 application, U.S. Patent Application No. 07/853,606 ("the '606 application"), on March 18, 1992, and then a subsequent CIP application from the '606 application, U.S. Patent Application No. 07/943,852 ("the '852 application") on September 11, 1992.

During the prosecution of the '852 application, the examiner issued an office action on June 23, 1993, that, among other things, rejected certain claims of the application. The examiner's statements pertinent to the present discussion read as follows:

> Claims 32, 33, 40, 41, 44, 45 and 48-51 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full,

[1] All cites to the specification of the '775 patent are to the '239 patent as well.

[2] The two patents asserted in this case relate to similar subject matter and relate back to an application, No. 10/198,845 ("the '845 application"), filed in 2002. The '239 patent is a divisional patent of the '845 application and was issued October 2, 2007. The '775 patent was issued July 4, 2006.

> clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Ex. 11 to Abbott's Mot. at ABT01362409-10.
>
> The specification is enabling only for claims drawn to a chimeric antibody which is characterized in having a human constant region and a mouse variable region. . . . The specification does not teach how to produce chimeric antibodies having less than an entire mouse variable regions which have properties required for therapeutic efficacy in the claimed methods. . . . The specification provides no direction or guidance to one skilled in the art as to how to produce such antibodies. Ex. 11 to Abbott's Mot. at ABT01362411 ("the chimeric rejection").
>
> The specification contemplates that antibodies according to the invention, which are used in the claimed methods, include human antibodies. The difficulties associated with obtaining stable cell lines secreting human antibodies having a particular desired binding specificity are well established in the art. The successful production of cell lines secreting human monoclonal antibodies is dependent upon the availability of a source of human immune lymphocytes producing an antibody of the desired specificity. Applicant has provided no evidence of the availability of sources of human lymphocytes producing high-affinity antibodies specific neutralizing epitopes of human TNF-alpha or which are capable of competitively inhibiting binding of monoclonal antibody A2 to TNF and which have [] properties required for successful therapeutic use. Ex. 11 to Abbott's Mot. at ABT01362421 ("the availability rejection").

The examiner then issued a notice of abandonment of the '852 application on January 24, 1994—Centocor did not address or otherwise respond to the examiner's June 23, 1993, rejections. *See* Ex. 12 to Abbott's Mot. at ABT01362435.

On February 2, 1993, prior to its abandonment of the '852 application, Centocor filed a CIP, U.S. Patent Application No. 08/013,413 ("the '413 application"). Claims 1-39 and 48-55 of the '413 application were identical to claims 1-39 and 42-49 of the parent '852 application. As with the '852 application, the same examiner issued an office action on October 27, 1993, rejecting claims 32, 33, 40-43, 50, 51, and 54-57 of the '413 application under 35 U.S.C. § 112, ¶¶ 1 & 2. The examiner used similar language in rejecting the '413 application claims as in the '852 application claims. *See* Ex. 15 to Abbott's Mot. at ABT01362952, -54-55 & -64-65.

Again, as with the '852 application, Centocor did not address or otherwise respond to the examiner's October 27, 1993, rejection. *See* Ex. 16 to Abbott's Mot. at ABT01362979. Instead, Centocor requested an extension of time to file another CIP application, premised upon its express abandonment of the '413 application. *See id*. The examiner granted the request and issued a notice of abandonment of the '413 application on May 25, 1994.

On February 4, 1994, Centocor filed three CIP applications—U.S. Patent Application Nos. 08/192,093 ("the '093 application"), 08/192,861 ("the '861 application"), and 08/192,102 ("the '102 application") (collectively, "the 1994 applications"). The alleged new matter added to the specification during the prosecution of the 1994 applications forms the basis of Abbott's acquiescence argument.

Abbott specifically points out and addresses five additions to the specification.[3]

1. "Anti-TNF antibodies (Abs) are intended to include at least one of monoclonal rodent-human chimeric antibodies, rodent antibodies, human antibodies or any portions thereof, having at least one antigen binding region of an immunoglobin variable region, which antibody binds TNF." *See* Ex. 7 to Abbott's Mot. at ABT01363021; '775 Patent, col. 5, ll. 55-59 ("human antibody reference").

2. Incorporation by reference of articles by Ausubel, Harlow, and Colligen.

   "Alternatively, the B lymphocyte can be transformed by providing a transforming gene or transforming gene product, as is well-known in the art. See, e.g., Ausubel infra, Harlow infra, and Colligan infra, the contents of which references are incorporated entirely herein by reference." *See* Ex. 7 to Abbott's Mot. at ABT01363037; '775 Patent, col. 15, ll. 7-9 (emphasis added) ("articles reference").

3. Inclusion of "or human" in the following sentence:

   "Such antibodies preferably include a murine or human anti-TNF variable region which contains a framework residue having complimentary determining residues which are responsible for antigen binding." *See* Ex. 7 to Abbott's Mot. at ABT 1363044;

[3] The court will cite to the '093 application; however, the same portions are also found in the '861 and '102 applications.

'775 Patent, col. 18, ll. 59-62 (emphasis added) ("or human reference").

4. Adding a reference to a "lambda phage display library" and citing an article by Dr. James Marks relating to phage display technology. *See* Ex. 7 to Abbott's Mot. at ABT01363043-44; '775 Patent, col. 18, ll. 48-53 ("phage library reference").

5. Adding an entire section, describing how anti-TNF-α antibodies can be rationally modified, including the following paragraph:

> Using this information, one of ordinary skill in the art will know how to achieve structural analogs of anti-TNF Abs and/or peptides, such as by rationally-based amino acid substitutions allowing the production of peptides in which the TNF binding affinity is modulated in accordance with the requirements of the expected therapeutic or diagnostic use of the molecule, preferably, the achievement of greater specificity for TNF binding. Ex. 7 to Abbott's Mot. at ABT01363070-73; '775 Patent, col. 33, l. 7 – col. 34, l. 45 ("structural analog reference").

Centocor does not object that the five disclosures identified by Abbott first appeared in the 1994 applications. The court will now turn to the merits of the motion.

III. Discussion

A. Summary Judgment

Summary judgment should be rendered "if the pleadings, the discovery and the disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). The evidence and pleadings must be viewed in the light most favorable to the party opposing summary judgment. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). Summary judgment is proper in a case where there is no genuine issue of material fact. *Celotex v. Catrett,* 477 U.S. 317, 322 (1986). "By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported

motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby*, 477 U.S. 242, 247-248 (1986)(emphasis in original).

The substantive law identifies material facts; disputes over facts that are irrelevant or unnecessary will not defeat a motion for summary judgment. *Id.* at 248. A "genuine" dispute about a material fact means that the evidence is "such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

B. Acquiescence and Estoppel

During patent prosecution, "[i]f the Examiner finally rejects a claim as lacking support in the disclosure, applicants generally have a choice. They may appeal the Examiner's decision on the merits . . . [or] they may elect to file a continuing application and reargue the point." *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 558 (Fed. Cir. 1994.). Otherwise, applicants can file a CIP application[4] "adding support for the rejected claims, thus restricting claims containing any new matter to the later filing date of the CIP." *Id.* at 559. When a dispute arises about the priority date for any particular claim that emerged from a CIP application, the "trial court must examine closely the prosecution history to discover the proper date for each claim at issue." *Id.*

A patentee is estopped from arguing that matter added in a CIP application is not new matter "when a clear, unambiguous rejection [gave] rise to a choice of appealing or accepting the rejection, and the applicant accept[ed] the rejection and expressly or impliedly concede[d] its correctness." *Id.* at 560 (finding there was no estoppel when the prosecution history showed the

[4] A CIP application is an application "filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said earlier nonprovisional application." Manual of Patent Examining and Procedure § 201.08 (emphasis in original) (citing *In re Klein*, 1930 C.D. 2, 393 O.G. 519 (Comm'r Pat. 1930)). A CIP patent "application can be entitled to different priority dates for different claims." *Waldemar*, 32 F.3d at 558. Claims that rely on new matter added in a CIP application are accorded the CIP application's filing date. *See Id.* Claims that do not rely on new matter are entitled to the priority date of the parent application. *Id.*

examiner had withdrawn his final rejection before a CIP was filed). Essentially, the applicant "implies that it did add new matter." *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1438 (Fed. Cir. 1984). Estoppel is a question of law for the court to decide. *Waldemar Link,* 32 F.3d at 558 (liking estoppel to prosecution history estoppel).

However, "the filing of a CIP application to overcome a PTO rejection does not . . . give rise to an irrebuttable presumption of acquiescence in the rejection." *Id.* at 1578. "As with any other basis for asserting patent invalidity," the party seeking to invalidate a patent "has the burden of overcoming the presumption of validity . . . by clear and convincing evidence that the filing of a CIP application and its issuance as a patent constituted an acquiescence" in a PTO rejection. *Pennwalt Corp. v. Akzona Inc.,* 740 F.2d 1573, 1578-79 (Fed. Cir. 1984). The burden of proof never shifts from the party seeking to invalidate the patent. *Id.* Nevertheless, "once a *prima facie* case of acquiescence is established, the patentee must come forward with countervailing evidence." *Id.* at 1579 (*citing TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984)). This does not relieve the challenger of his burden, nor may the patent owner escape coming forward with an explanation. *See Id.* This "means that if a *prima facie* case is made . . . the patent owner must be able to point to or must come forward with convincing evidence to counter that showing." *TP Labs.,* 724 F.2d at 971. A *prima facie* case of acquiescence is made when the challenger presents clear and convincing evidence that: (1) the patent examiner issued a clear, unambiguous, and final 35 U.S.C. § 112 rejection; and (2) the patentee expressly or impliedly conceded the correctness of the rejection by filing a CIP application in response. *See Pennwalt*, 740 F.2d at 1579; *Waldemar Link,* 32 F.3d at 559-60.

C. Acquiescence – Application

1. Clear, Unambiguous, and Final 35 U.S.C. § 112 Rejection

As *Pennwalt* and *Waldemar Link* counsel, in assessing whether Abbott makes a *prima facie* case of acquiescence, the court will first determine whether the examiner made "a clear, unambiguous rejection" of enablement.[5] As discussed above, on June 23, 1993, the PTO issued an office action, rejecting claims 32, 33, 40, 41, 44, 45, and 48-51 under 35 U.S.C. § 35, ¶¶ 1 and 2. *See* Ex. 11 to Abbott's Mot. at ABT01362409-10, -11 & -21. In support of its acquiescence argument concerning enablement, and as indicated above, Abbott directs the court to three citations in both the '852 and '413 patent applications—the introductory language of paragraph 22 (paragraph 26 of the '413 patent application), the chimeric rejection, and the availability rejection. Centocor objects to Abbott's interpretation of the rejections and instead argues that each is irrelevant for the purposes of enablement of human antibodies—at a minimum, Centocor suggests, there is a genuine issue of material fact as to whether the rejections concern enablement. As discussed below, the court disagrees with Centocor's conclusion.

Turning to the rejections at issue, the introductory language of paragraph 22 states, "claims . . . are rejected under 35 U.S.C. § 112, first and second paragraph, as the claimed invention is not described in full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same . . . ." *Id*. at ABT01362409-10; *see also* Ex. 15 to Abbott's Mot. at ABT01362952 (using similar language regarding the '413 application). On the following page, still within paragraph 22, the examiner states, "The specification is enabling only for claims drawn to a chimeric antibody which is characterized in having a human constant region and a mouse variable region. . . . The specification does not teach how to produce

[5] Here, the rejections concern 35 U.S.C. § 112, ¶ 1, enablement; however, the court notes that it can discern no requirement that the rejection be specific for enablement. *See Pennwalt*, 740 F.2d at 1578-79; *Waldemar Link*, 32 F.3d at 558-60.

chimeric antibodies having less than an entire mouse variable regions which have properties required for therapeutic efficacy in the claimed methods." Ex. 11 to Abbott's Mot. at ABT01362410; *see also* Ex. 15 to Abbott's Mot. at ABT01362954 (using similar language regarding the '413 application). In its opposition to the characterization of the chimeric rejection as one of enablement, Centocor argues that the rejection is, in fact, an indefiniteness rejection; specifically, Centocor urges that Abbott, through improper simplification of quotes, misrepresents the examiner's rejections. A reading of the rejection indicates quite the opposite. Centocor's argument is contradicted by the express language of the introductory language and the rejection itself. The rejection language, read in the context of paragraph 22 as a whole, clearly and unambiguously indicates that the examiner rejected the claims on enablement grounds. *Id*. Furthermore, Centocor's patent law expert agrees that the chimeric rejection is one of enablement, as indicated first in his report and subsequently confirmed in his testimony during deposition. *See* Ex. 25 to Abbott's Mot. at 28; Ex. 6 to Abbott's Reply at p. 148, l. 5 – p. 150, l. 13.

As to the availability rejection, Centocor concedes that it is one of enablement; however, it asserts that the rejection is directed towards the *availability* of human immune lymphocytes that could be used to produce fully human antibodies. Such an argument, however, is inapposite. *See* Ex. 11 to Abbott's Mot. at ABT01362421 ("successful production . . . is dependent upon the availability . . . ."). In light of the specification's contemplation of human antibodies, to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1, a patentee must fully, clearly, and concisely describe how to make and use claims directed towards human antibodies. Concerning the availability rejection, it is clear from the office actions regarding the '852 and '413 patent applications that the claims directed towards human antibodies fail for lack of enablement.

As Abbott correctly asserts, the prosecution history of the patents-in-suit show that the examiner issued enablement rejections directed towards claims of the '852 and '413 applications. Accordingly, Abbott has met its initial showing.

2. Implied Concession

As the clear and unambiguous rejections of the '852 and '413 patent applications "g[a]ve rise to a choice of appealing or accepting the rejection," the court will now determine if Abbott has met its burden of showing that Centocor either expressly or impliedly conceded the correctness of the rejections. *See Waldemar Link*, 32 F.3d at 560. Under the facts of this case, the crux of determining acquiescence is not in the finding of an express or affirmative act on the part of Centocor, but in the finding of implicit concession by Centocor's failure to act in the face of the chimeric and availability rejections, except to file a CIP.

Turning to the added matter in the 1994 applications, first, it is evident that the human antibody and "or human" references were added in direct response to the chimeric rejection. As addressed above, the chimeric rejection indicates that the patent was not enabled for claims directed towards fully human antibodies, stating, "the specification is enabling only for claims drawn to a chimeric antibody which is characterized in having a human constant region and a mouse variable region." Ex. 11 to Abbott's Mot. at ABT01362411. The chimeric rejection expressly addresses a less than fully human antibody—the human antibody reference expressly contemplates a fully human antibody, and the "or human" reference expressly contemplates a human variable region. *See* Ex. 7 to Abbott's Mot. at ABT01363021, -44; '775 Patent, col. 5, ll. 55-62. That the human antibody and "or human" references address fully human antibodies is further supported by Centocor's reliance upon both the human antibody reference and "or human" reference during the claim construction phase, as well as in its answer to interrogatory

no. 17.[6] In addition, the phage library reference also addresses the chimeric rejection. Its discussion of an "alternative way of cloning an anti-TNF variable or constant region," is directed towards the expression of a human variable region. *See* Ex. 7 to Abbott's Mot. at ABT01363043-44; '775 Patent, col. 18, ll. 48-53.

With respect to the articles reference, this sentence was appended to the specification immediately after a sentence discussing B lymphocyte transformation. As discussed above, the availability rejection states that the patent was not enabled because it did not disclose "the availability of sources of human lymphocytes producing high-affinity antibodies." Ex. 11 to Abbott's Mot. at ABT01362421. The availability rejection expressly addresses the lack of evidence of the availability of sources of human lymphocytes—the articles reference expressly addresses the availability of human lymphocytes. *See* Ex. 7 to Abbott's Mot. at ABT01363037; '775 Patent, col. 15, ll. 7-9.[7]

The structural analog reference also addresses the availability rejection, specifically, the portion addressing binding specificity. The structural analog reference is directed to "the production of peptides in which the TNF binding affinity is modulated in accordance with the requirements of the expected therapeutic or diagnostic use of the molecule, preferably, the achievement of greater specificity for TNF binding." *See* Ex. 7 to Abbott's Mot. at

[6] As indicated in the April 6, 2009, claim construction opinion, the court found the human antibody reference persuasive in support of its construction of the human terms. *See* '775 Patent, col. 5, ll. 55-59; Claim Construction Opinion, Dkt. No. 150, at 11-12 (April 6, 2009). Interrogatory No. 17 asked Centocor to identify those portions of the specifications of the patents-in-suit that it contends demonstrate support for the written description requirement of 35 U.S.C. § 112, ¶ 1 for fully human anti-TNF-α antibodies. In response, Centocor listed, among others, the human antibody, articles, "or human," and phage library references for support that the patents describe "anti-TNF-α antibodies containing constant regions and variable regions encoded by genes derived from human DNA." *See* Ex. 55 to Abbott's Reply.

[7] Centocor argues that the addition goes to transformation and not availability. The court does not read the added matter in the same vein. The relevant section begins, "The antibody-producing cell contributing to nucleotide sequences encoding the antigen-binding region of the chimeric antibody of the present invention can also be produced by transformation of a non-human, such as a primate, or a human cell. For example, a B lymphocyte which produces anti-TNF antibody can be infected and transformed with a virus such as Epstein-Barr virus to yield an immortal anti-TNF producing cell . . . ." Ex. 7 to Abbott's Mot. at ABT01363037.

ABT01363070-73; '775 Patent, col. 33, l. 7 – col. 34, l. 45. TNF binding relates to the variable region of an antibody, and the structural analog reference discusses a number of ways to increase desirable characteristics, such as specificity.

The evidence and arguments before the court indicate that the five references, each of which Centocor agrees was added in 1994, were directed towards either the chimeric or availability enablement rejections. Much like in *Pennwalt*, the court finds that the 1994 CIP applications added references relating to both the chimeric and availability rejections. As with its preliminary showing, Abbots has met its subsequent showing and has thus made a *prima facie* case of acquiescence—"the filing of a CIP application and its issuance as a patent constituted an acquiescence by [Centocor] in the PTO's rejection." *Pennwalt*, 740 F.2d at 1578-79.

3. Countervailing Evidence

Although Abbott has the burden of overcoming the presumption of validity, "once a *prima facie* case of acquiescence is established, [Centocor] must come forward with countervailing evidence." *Id*. After a thorough review of the record, it is apparent that Centocor presents no evidence to refute the *prima facie* case of acquiescence to the PTO's chimeric and availability enablement rejections.

In rebuttal, Centocor argues that the examiner of the '775 application deemed that the patent was enabled and entitled to a priority date of March 18, 1991; that Centocor's counsel testified that the CIP applications were filed to add subsequently generated research; and that the enablement of the patents prior to 1994 is sharply contested. *See* Ex. 2 to Centocor's Resp. at CCOR 00000426; Ex. 4 to Centocor's Resp. at 316-17. The court finds each argument of no influence. Acquiescence, like estoppel, is a legal question for the court; accordingly, "this court reviews an estoppel based on what occurred during prosecution . . . Thus, whether estoppel

applies in the circumstances of this case is a conclusion of law . . . ." *See Waldemar Link*, 32 F.3d at 558. Here, the court looks at the legal effect of the filing of the CIP in the face of two enablement rejections. The merits of enablement, the examiner's rejection, and a subsequent examiner's conclusions are of no importance in the court's acquiescence analysis.[8] With respect to the assertion that the five references represent "subsequent data and updating information," the court is not persuaded that such a broad statement sufficiently rebuts a *prima facie* case of acquiescence, even under the summary judgment standard. *See* Ex. 4 to Centocor's Resp. at 303:11 – 305:13. Upon a showing of acquiescence, Centocor failed to present evidence addressing the reasons for including the new references in the 1994 CIP applications. Accordingly, Centocor has not presented countervailing evidence to rebut the *prima facie* case of acquiescence.

D. Anticipation

A reference is anticipatory under 35 U.S.C. § 102(b) when it satisfies particular requirements. First, the reference must disclose each and every element of the claimed invention, whether it does so explicitly or inherently. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.,* 471 F.3d 1369, 1375 (Fed. Cir. 2006). Second, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.,* 545 F.3d 1312, 1314 (Fed. Cir. 2008); *see In re LeGrice,* 301 F.2d 929, 940-44 (1962). As long as the reference discloses all of the claim limitations and enables the "subject matter that falls within the scope of the claims at issue," the reference anticipates—no "actual creation or reduction to practice" is required. *Schering Corp. v. Geneva Pharms., Inc.,*

[8] "Our holding on the threshold question of whether Armak acquiesced in the PTO's rejections and, therefore, could not gain the benefit of the grandparent application's filing date makes it unnecessary to decide whether the district court correctly reached the same result based on its conclusions regarding the secondary questions of whether the claims of the Nemeth patent were supported by the disclosure of the grandparent application or whether the grandparent application *actually* met the enablement and best mode requirements of section 112 (first paragraph)." *Pennwalt*, 740 F.2d at 1580.

339 F.3d 1373, 1380-81 (Fed. Cir. 2003); *see In re Donohue,* 766 F.2d 531, 533 (Fed. Cir. 1985). This is so despite the fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent. *See Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1562 (Fed. Cir. 1991) (discussing the "distinction between a written description adequate to *support* a claim under § 112 and a written description sufficient to *anticipate* its subject matter under § 102(b)"). Anticipation is a question of fact, including whether an element is inherent in the prior art. *Eli Lilly,* 471 F.3d at 1375. Additionally, under 35 U.S.C. § 112, "[w]hether a prior art reference is enabling is a question of law based upon underlying factual findings." *Minn. Mining & Mfg. Co. v. Chemque, Inc.,* 303 F.3d 1294, 1301 (Fed. Cir. 2002).

E. Anticipation – Application

Abbott also contends that the patents-in-suit are anticipated by a foreign patent application, the 1992 Le Application. The 1992 Le application is the foreign counterpart to the U.S. applications leading to the Centocor patents. It has an effective date of October 1, 1993, and is substantially identical to the '852 application. As the doctrine of acquiescence applies, Abbott argues, the Le application anticipates the patents-in-suit. The court is not persuaded by Abbott's argument. On one hand, Abbotts asserts that the patents-in-suit are entitled to a priority date of no later than February 4, 1994, suggesting that the patents-in-suit are not enabled prior to 1994. On the other hand, Abbott asserts that the 1992 Le application, which is substantially identical to the '852 application, anticipates the patents-in-suit. As the law requires enablement in order to anticipate, these two arguments appear inconsistent.

The outcome in this case depends largely on the facts. Although it was not necessary to determine enablement in the context of acquiescence, it is necessary to do so here. For a reference to be anticipatory, it must enable one of skill in the art to make the invention without

undue experimentation. *See In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In this instance, the court has made its finding regarding the legal effect of acquiescing to enablement rejections on the priority date, without addressing the underlying question of enablement. As the determination of enablement rests upon underlying facts and Abbott has not shown that there is no genuine issue as to any material fact, the court denies Abbott's motion that the patents-in-suit are anticipated by the 1992 Le application.

IV. Conclusion

Having found that Abbott has established a *prima facie* case of acquiescence (showing that the PTO examiner made clear, unambiguous, and final enablement rejections, and that Centocor impliedly conceded the correctness of the rejections by filing the 1994 CIP applications in response), and that Centocor failed to present countervailing evidence, the court finds that Centocor is estopped from asserting that the '827, '606, '852, and '413 applications complied with the first paragraph of 35 U.S.C. § 112 in order to gain benefit of those application's filing dates. Finally, as anticipation is a question of fact, the court denies Abbott's motion to the extent that it seeks to invalidate the patents-in-suit as anticipated under 35 U.S.C. § 102(b).

SIGNED this 27th day of May, 2009.

T. John Ward

T. JOHN WARD
UNITED STATES DISTRICT JUDGE